ST. JUDE MEDICAL
MORE CONTROL. LESS RISK

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Corporate ID no: 556335-9446

DEC 2 0 2013

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements in 21 CFR §807.92

Submitted by:	St. Jude Medical Systems AB Palmbladsgatan 10, Box 6350 SE-751 35 Uppsala, Sweden Phone:+46 18 161000 Fax: +46 18 161099
Contact Person:	Ellinor Nami
Date Prepared:	November 15, 2013
Proprietary Name:	PressureWire™
Common Name:	PressureWire™ Guidewire
Classification Name:	Transducer, Pressure, Catheter Tip (870.2870) Wire, Guide, Catheter (870.1330) Transmitters and Receivers, physiological signal, radiofrequency (870.2910)
Predicate Device:	(K131452) PressureWire™ Aeris™ cleared September 5, 2013 PressureWire™ Aeris™ and PressureWire™ Receiver™, K080813, cleared July 1, 2008.

Device Description:

The subject device, PressureWire™ Aeris™, is a new version of the predicate device (K131452), with the same name. The PressureWire has an integrated sensor element at the tip to enable measurements of physiological parameters. The wire is introduced into the patient's blood vessel. A torque device is used to steer the wire and sensor into the required position for pressure measurements according to standard clinical practice. PressureWire is available in two different lengths.

The guidewire is uniquely paired with a specific connection cable for PressureWire Certus (not subject device for this submission) or with a specific transmitter for PressureWire Aeris (subject device). Both PressureWire connection configurations connect to a diagnostic computer or a catheter laboratory hemodynamic recording system.

Indication for Use:

PressureWire™ is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels.

Predicate Device Comparison:

PressureWire was cleared by FDA under 510(k) K131452 on September 5, 2013. The subject device is substantially equivalent to the predicate device in terms of intended use, indication for use, operational

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characteristics, and fundamental design and technology characteristics. Below list identifies the changes to the subject device.

- Change to PressureWire Aeris Transmitter Hardware
- Change to PressureWire Aeris Transmitter Software
- Change to PressureWire Aeris Transmitter Enclosure
- Change to PressureWire Aeris packaging
- Change to PressureWire Aeris IFU
- Change to the sterilization cycle

Testing summary:

A summary of PressureWire™ Design Control Activities with regards to risk analysis and verification and validation activities is provided in this 510k submission. The modifications applies to the transmitter part of the PressureWire™ Aeris™ and do not change the operational principle. The successful completion of verification activities demonstrates that PressureWire™ meets the required product specifications. Based on passing verification specification criteria for mechanical and signal testing, PressureWire™ performs substantially equivalent to predicate devices.

Substantial Equivalence:

The fundamental scientific technology for the subject device is the same as for predicate device regarding signal transfer, mechanical properties and intended use. Pressure Wire is substantially equivalent to the predicated device in intended use, indication for use, fundamental design and technology, and operating principles. Both devices connect to a diagnostic computer or a catheter laboratory hemodynamic recording system to enable measurements of physiological parameters with minor changes incorporated into the Pressure Wire from the predicate device including:

- Change to PressureWire Aeris Transmitter Hardware
- Change to PressureWire Aeris Transmitter Software
- Change to PressureWire Aeris Transmitter Enclosure
- Change to PressureWire Aeris packaging
- Change to PressureWire Aeris IFU
- Change to the sterilization cycle

The subject device, PressureWire™ Aeris™, meets the design inputs and raises no new safety or efficacy concerns. PressureWire™ is determined to be substantially equivalent to the presently marketed predicate device, K131452.

Conclusion:

Based on the similarities in indication for use, design features and functional features, the modified PressureWire™ Aeris™ is substantially equivalent to the currently marketed predicate device PressureWire™ Aeris™, K131452.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

St. Jude Medical Systems Ab
Erdulfo De Peralta
4 Robbins Rd.
Westford, MA 01886 US

Re: K133587
Trade/Device Name: PressureWire Aeris Agile Tip; PressureWire Aeris Agile Tip 300
Regulation Number: 21 CFR 870.1330
Regulation Name: Pressure Wire Guide Wire
Regulatory Class: Class II
Product Code: DRG, DQX, DXO
Dated: November 18, 2013
Received: November 21, 2013

Dear Erdulfo De Peralta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K133587

Indications for Use Statement

510(k) Number (if known) K133587

Device Name PressureWire

Indications for Use PressureWire™ is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____X___ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Digitally signed by
Owen P. Faris -S
Date: 2013.12.20
16:22:48 -05'00'